

Application Serial No. 10/750,270  
Amendment & Response to Office Action dated December 20, 2005

**REMARKS**

Claims 1-46 are pending. Reconsideration of the claims based on the below comments is respectfully requested.

**Examiner Interview**

The Applicants' representative (John Gatz) would like to thank the Examiners for the interview of February 28, 2006. The pending claims and the applied reference of U.S. Patent No. 5,856,195 to Charlton ("Charlton") were discussed. No decision was made on the patentability of the claims at that time and the Examiners recommended filing a formal response for further consideration.

**In The Specification**

The Applicant previously claimed priority back to Application No. 60/440,860, which was filed on January 21, 2003 in the declaration. See Exhibit 1. The declaration was submitted within the time period set forth in 37 C.F.R. 1.78(a). The Patent Office acknowledged priority to Application No. 60/440,860 in its filing receipt. See Exhibit 2. The Applicant inadvertently did not include the claimed priority in the first sentence of the specification. The Applicant has added a Cross-Reference to Related Application section that includes the claimed priority to Application No. 60/440,860 as the first sentence of the specification. Pursuant to MPEP 201.11, since the declaration was timely filed and the information concerning the benefit claim was recognized by the Patent Office as shown by its inclusion on the first filing receipt, a petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Therefore, the Applicant respectfully requests that the Cross-Reference to Related Application section be added to the present application.

**35 U.S.C. § 102(b) Rejections**

**Independent Claims 1, 22 and 39**

The pending claims have three independent claims (claims 1, 22 and 39). Claim 1 recites, *inter alia*, (a) "a single calibration input element adapted to permit a user to input the calibration number, one digit at a time, associated with the test sensor"; (b) "a processor electronically coupled to the single calibration input element..."; and (c) a user display electronically coupled to the processor for displaying digits to be selected by a user inputting the calibration number...."

Claim 22 recites, *inter alia*, (a) "prompting a user, via a user display, to enter a digit of the calibration number"; (b) receiving input from the user, via a single calibration input element, indicative of the calibration number, one digit at a time"; and (c) "determining the analyte concentration in the sample in response to receiving the calibration number from the user and measuring the reaction." Claim 39 recites, *inter alia*, (a) a single calibration input element adapted to permit the user to select digits for inputting a multiple-digit calibration number, one

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digit at a time"; and (b) "a processor electronically coupled to the single calibration input element and the user display, the processor prompting the user to input each of the digits of the calibration number, one at a time, the processor receiving the inputted calibration number and adjusting the at least one adjustable parameter of the concentration equation according to the stored adjustment corresponding to the inputted calibration number."

The applied reference of U.S. Patent No. 5,856,195 to Charlton ("Charlton") does not disclose, let alone teach or suggest, the above features in independent claims 1, 22 and 39. Rather, Charlton discloses "calibration codes assigned for use in the clinical value computations to compensate for manufacturing variations between sensor lots are encoded upon a tag or label generally designated by 70 that is associated with a sensor package 50 of sensors 32, as shown in FIG. 4. The calibration encoded label 70 is inserted into the instrument with the package 50 of multiple sensors 32 which are stored in individual blisters 33 and read by associated sensor electronic circuitry before a sensor 32 is used." Col. 4, lines 1-10 of Charlton (emphasis added). In summary, Charlton discloses that the calibration codes are located on the sensor package and read by the instrument. Independent claims 1, 22 and 39, on the other hand, have specific limitations discussed above generally associated with a single calibration input element adapted to permit a user to input the calibration number or an act of the user inputting the calibration number via the single calibration input element.

In the Office Action dated December 20, 2005, various references are made to FIGS. 7A-7D and 6B of Charlton. See pages 10 and 11. FIG. 6B of Charlton shows an enlarged view of a calibration encoded label 70 that "is used to automate the process of information transfer about the lot specific reagent calibration assignment for associated sensors 32." Col. 5, lines 29-35. The calibration encoded label 70 is read at any angular position and deciphered by the sensor meter without any user intervention." Col. 5, lines 39-42 of Charlton (emphasis added). FIGs. 7B and 7C of Charlton also include respective calibration encoded labels 170, 170A. Thus, the statements that "the device shown in FIG. 6 [FIG. 6B] allows [] a user to input a calibration number (see FIG. 7C) through a calibration input element" and "the Charlton system is capable to select a number calibration through [an] input element" are incorrect. See page 11 of the Office Action.

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Independent claims 1, 22 and 39, on the other hand, have specific limitations discussed above generally associated with a single calibration input element adapted to permit a user to input the calibration number or an act of the user inputting the calibration number via the single calibration input element. Therefore, independent claims 1, 22 and 39 are not anticipated by or rendered obvious over Charlton and are in a condition for allowance. Dependent claims 2-21, 23-38 and 40-46, which depend either directly or indirectly on independent claim 1, 22 or 39, should also not be anticipated by or rendered obvious over Charlton for at least the same reasons as discussed above in connection with independent claims 1, 22 and 39. Thus, claims 2-21, 23-38 and 40-46 also should be in a condition for allowance.

Therefore, independent claims 1, 22 and 39 are not anticipated by or rendered obvious over Charlton and are in a condition for allowance.

#### **Dependent Claims**

Claims 7-10 and 40 were objected to. Dependent claims 2-21, 23-38 and 40-46, which depend either directly or indirectly on independent claim 1, 22 or 39, should also not be anticipated by or rendered obvious over Charlton for at least the same reasons as discussed above in connection with independent claims 1, 22 and 39. Thus, claims 2-21, 23-38 and 40-46 also should be in a condition for allowance.

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Conclusion

The Applicant submits that the claims are in a condition for allowance and action toward that end is earnestly solicited. It is believed that no fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Bayer Healthcare LLC Deposit Account No. 13-3375(MSE-#2672).

Respectfully submitted,



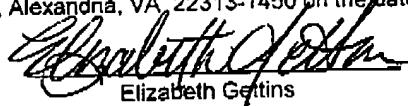
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March 17, 2006



Elizabeth Gertins